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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/922,240	08/27/1997	STUART L. SCHREIBER	APBI-P01-007	1342

28120 7590 10/22/2002

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BOSTON, MA 02110-2624

EXAMINER

SHUKLA, RAM R

ART UNIT PAPER NUMBER

1632

DATE MAILED: 10/22/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

**Advisory Action**

Application N .

08/922,240

Applicant(s)

SCHREIBER ET AL.

Examiner

Ram R. Shukla

Art Unit

1632

—The MAILING DATE of this communication appears on the cover sheet with the correspondence address —

THE REPLY FILED 04 October 2002 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

**PERIOD FOR REPLY** [check either a) or b)]

- a) ☐ The period for reply expires \_\_\_\_\_ months from the mailing date of the final rejection.
- b) ☒ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on \_\_\_\_\_. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☒ The proposed amendment(s) will not be entered because:
- (a) ☒ they raise new issues that would require further consideration and/or search (see NOTE below);
  - (b) ☒ they raise the issue of new matter (see Note below);
  - (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
  - (d) ☒ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: See Continuation Sheet.

3. ☐ Applicant's reply has overcome the following rejection(s): \_\_\_\_\_.
4. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☐ request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☒ will not be entered or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:


Claim(s) allowed: 32,33,36 and 44.

Claim(s) objected to: \_\_\_\_\_.

Claim(s) rejected: 1-27, 29-31, 38-43.

Claim(s) withdrawn from consideration: \_\_\_\_\_.

8. ☐ The proposed drawing correction filed on \_\_\_\_\_ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_.
10. ☒ Other: See Continuation Sheet

  
**RAM R. SHUKLA, PH.D**  
**PATENT EXAMINER**

Ram R. Shukla  
Examiner  
Art Unit: 1632

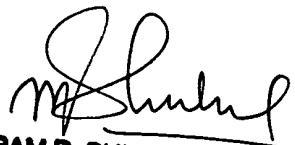
Continuation of 2. NOTE: Applicants' proposed amendments raise new issues that require further search and consideration. For example, claim 26 has added the limitations of allogeneic or xenogeneic, which will require new search and consideration. The issues in the process of an autologous transplantation are different and distinct than those in allogeneic or xenogeneic transplantation. Likewise, applicants' proposed amendments raise new matter issue. For example, applicants have introduced the term "preferentially" in claims 1, 16, 18, and 39. However, the specification does not provide support for this term. The specification only describes the term "selectively". It is noted that scopes of the terms "selectively" and "preferentially" differ significantly. The term "selectively" excludes inhibition in any other cells except the target cells whereas "preferentially" will include occurrence of the phenomenon in all cells except that target cells will be preferred. It is further noted that applicants have stated in their response that no new matter has been introduced, however, they have not indicated as to where in the specification the proposed amendments have been described. The proposed amendment also raises new 112 second issues. For example, claim 1 as proposedly amended recites a method for inhibiting T cells, however, inhibition is a term used for a reaction or a process. it is not clear as to how T cells will be inhibited since a T cell is not an enzyme or a process.

Continuation of 5. does NOT place the application in condition for allowance because: Applicants' arguments have been fully considered, however, they are not persuasive. While applicants have proposed amendments to the pending independent and dependent claims, these amendments do not address the enablement issues set forth in the previous office actions. Applicants have not provided any new evidence to support their arguments, rather have reiterated their previous arguments. Applicants have further argued that 116 patents issued between 1991-1995 have rapamycin, FK506 or cyclosporine in claims, however this statement does not provide enabling disclosure for the instantly claimed invention. Applicants did not cite any specific patent which would have provided evidence that the instantly claimed invention was enabled.

Continuation of 10. Other:

The Examiner prosecuting this application has been changed. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ram R. Shukla whose telephone number is (703) 305-1677. The examiner can normally be reached on Monday through Friday from 7:30 am to 4:00 p.m. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached on (703) 305-4051. The fax phone number for this Group is (703) 308-4242. Any inquiry of a general nature, formal matters or relating to the status of this application or proceeding should be directed to the Dianiece Jacobs whose telephone number is (703) 305-3388.

Ram R. Shukla, Ph.D..

  
**RAM R. SHUKLA, PH.D**  
**PATENT EXAMINER**